

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA**

TRIVITIS, INC.,

Plaintiff,

vs.

OCEAN SPRAY CRANBERRIES, INC.,

Defendant.

CASE NO. 10cv0316 JM(MDD)

ORDER GRANTING MOTION TO
EXCLUDE EXPERT TESTIMONY;
GRANTING OCEAN SPRAY'S
MOTION FOR SUMMARY
JUDGMENT; DENYING
PLAINTIFF'S MOTION FOR
SUMMARY JUDGMENT

Trivitis, Inc. ("Trivitis") and Ocean Spray Cranberries, Inc. ("Ocean Spray") separately move for summary judgment pursuant to Federal Rule of Civil Procedure 56. Ocean Spray also moves to exclude the expert testimony of Drake Larson and Dale Shellhamer. All motions are opposed. Having carefully considered the matters presented, appropriate legal authorities, the court record, and for the reasons stated below, the court grants the motion to exclude the expert testimony of Drake Larson and Dale Shellhamer, grants Ocean Spray's motion for summary judgment, denies Plaintiff's motion for summary judgment, and instructs the Clerk of Court to close the file.

BACKGROUND

On February 10, 2010, Trivitis commenced this federal question action alleging a single claim for patent infringement. Trivitis is the alleged owner of the Patent entitled "Catechin Multimers as Therapeutic Drug Delivery Agents," U.S. Patent No. 6,562,864 (the "'864 Patent" or the "Patent"). (Compl. ¶8; Ocean Spray Exh. A). Trivitis alleges that Ocean Spray is infringing its patent rights by making, using, offering to sell or selling "products that practice inventions claimed in the '864 Patent,

1 including but not limited to, its CRANERGY Energy Juice Drink.” (Compl. ¶10).

2 The Allegedly Infringing Product

3 Ocean Spray produces a drink called Cranergy that allegedly infringes claims 10 and 11 of the
 4 ‘864 patent. (Compl. ¶10; Trivitis Brief at p.2:3-9). Cranergy is a cranberry juice drink “enhanced
 5 with natural caffeine from green tea extract and added B Vitamins.”
 6 [Http:”“www.oceanspray.com/products/Cranergy. Aspx..](http://www.oceanspray.com/products/Cranergy.Aspx..) The drink is marketed as a “naturally
 7 energizing juice drink” that provides a “little help to get through your busy day.” Id.

8 The Patent Claims

9 At issue are Claims 10 and 11 of the Patent:

10 **Claim 10.** A therapeutic composition comprising a bioactive agent complexed with
 11 a carrier agent, wherein said bioactive agent is cationic or nucleophilic and said carrier
 agent comprises a catechin multimer.

12 **Claim 11.** The composition of claim 10, wherein said catechin multimer comprises
 13 a substituted catechin multimer.

14 Claims Construction

15 On August 18, 2011 the court issued an order construing five disputed terms of the ‘864 Patent.
 16 The court adopted the following constructions.

17 **Cationic:** “positively charged, electron accepting molecule that forms a bond to its reactive
 18 partner.”

19 **Nucleophilic:** “negatively charged, electron donating molecule that forms a bond to its
 20 reaction partner.”

21 **Catechin:** “a molecule with the following formula: [followed by a diagramed molecule, Patent
 22 Col. 5:8-17].”

23 **Multimer:** “multivalent or multimeric forms of the compounds of interest made by linking
 24 multiple copies (two or more) of a compound (namely catechin) to each other and depicted as
 25 [followed by a diagram, Patent Col. 4:19-34.]”

26 **Complexed:** “the bioactive agent is bound (an affinity or attraction of varying degree) to the
 27 carrier agent sufficient for the delivery of the bioactive agent to target sites.”

28 ///

The Infringement Contentions

In its infringement contentions, Trivitis alleges that Cranergy's green tea extract contains epigallocatechin gallate, the "catechin multimer," and Niacin (Vitamin B3), the "bioactive agent." According to the contentions, "Niacin will readily 'bind' and/or 'coordinate' with the catechin multimers of the green tea extract, and assemble into complexes as claimed." (Ocean Spray Exh. D at 2:28-3:4).

Trivitis asserts that “each element of the asserted claims is present” in the Cranergy drink. Alternatively, if any element is not “found to be literally present in [Cranergy] it is present under the doctrine of equivalents.” (Id. at p.2:23-25).

DISCUSSION

Legal Standards

Summary Judgment Legal Standards

A motion for summary judgment shall be granted where “there is no genuine issue as to any material fact and . . . the moving party is entitled to judgment as a matter of law.” FED. R. CIV. P. 56(c); Prison Legal News v. Lehman, 397 F.3d 692, 698 (9th Cir. 2005). The moving party bears the initial burden of informing the court of the basis for its motion and identifying those portions of the file which it believes demonstrate the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). There is “no express or implied requirement in Rule 56 that the moving party support its motion with affidavits or other similar materials negating the opponent’s claim.” Id. (emphasis in original). The opposing party cannot rest on the mere allegations or denials of a pleading, but must “go beyond the pleadings and by [the party’s] own affidavits, or by the ‘depositions, answers to interrogatories, and admissions on file’ designate ‘specific facts showing that there is a genuine issue for trial.’” Id. at 324 (citation omitted). The opposing party also may not rely solely on conclusory allegations unsupported by factual data. Taylor v. List, 880 F.2d 1040, 1045 (9th Cir. 1989).

The court must examine the evidence in the light most favorable to the non-moving party. United States v. Diebold, Inc., 369 U.S. 654, 655 (1962). Any doubt as to the existence of any issue of material fact requires denial of the motion. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255

(1986). On a motion for summary judgment, when “‘the moving party bears the burden of proof at trial, it must come forward with evidence which would entitle it to a directed verdict if the evidence were uncontroverted at trial.’” Houghton v. South, 965 F.2d 1532, 1536 (9th Cir. 1992) (emphasis in original) (quoting International Shortstop, Inc. v. Rally's, Inc., 939 F.2d 1257, 1264-65 (5th Cir. 1991), cert. denied, 502 U.S. 1059 (1992)).

Patent Infringement

Determination of patent infringement is a two-step procedure. “First, the claim must be properly construed to determine its scope and meaning. Second, the claim as properly construed must be compared to the accused device or process.” Terlep v. Brinkman Corp., 418 F.3d 1379, 1381 (Fed.Cir. 2005) (quoting Carroll Touch, Inc. v. Electro Mech. Sys., Inc., 15 F.3d 1573, 1576 (Fed.Cir.1993)). Claim construction is an issue of law, see Markman v. Westview Instruments, Inc., 52 F.3d 967, 970–71 (Fed.Cir.1995) (en banc), aff'd, 517 U.S. 370 (1996), that is reviewed de novo by the Federal Circuit. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed.Cir.1998) (en banc). Infringement, on the other hand, is a question of fact. Terlep, 418 F.3d at 1381 (citing Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353 (Fed.Cir.1998)). Where the facts underlying the issue of infringement are undisputed, the function of applying claims to the accused device is the province of the district court. Martin v. Barber, 755 F.2d 1564, 1567 (Fed.Cir.1984).

The Motion to Exclude Testimony of Plaintiff's Experts (Drake Larson and Dale Shellhamer)

The primary evidence submitted by Trivitis in support of its motion for summary judgment, and in opposition to Ocean Spray's motion, consists of the declarations and testimony of Drake Larson, the CEO of Trivitis, and Dale Shellhamer, Ph.D. Ocean Spray contends that Mr. Larson's testimony must be excluded because (1) he lacks the training or knowledge needed to qualify him as an expert and (2) it is not based on reliable testing within the meaning F.R.E. 702. Ocean Spray also seeks to exclude the testimony of Mr. Shellhamer because (1) it relies entirely upon the flawed and unreliable data produced by Mr. Larson and (2) his two page report is entirely conclusory.

Pursuant to the recently revised Federal Rule of Evidence 702,

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

(a) the expert's scientific, technical, or other specialized knowledge will help the trier

- 1 of fact to understand the evidence or to determine a fact in issue;
- 2 (b) the testimony is based on sufficient facts or data;
- 3 (c) the testimony is the product of reliable principles and methods; and
- 4 (d) the expert has reliably applied the principles and methods to the facts of the case.

5 Before admitting expert testimony, the trial court must conduct “a preliminary assessment of

6 whether the reasoning or methodology underlying the testimony is scientifically valid and of whether

7 that reasoning or methodology properly can be applied to the facts in issue.” Daubert v. Merrell Dow

8 Pharmaceuticals, Inc., 509 U.S. 579, 592-93 (1993); Kumho Tire Co., Ltd. v. Carmichael, 526 U.S.

9 137, 147 (1999) (holding that Daubert applies to “all expert testimony”). “The focus, of course, must

10 be solely on principles and methodology, not on the conclusions that they generate.” Id. at 593. The

11 proffered expert must be “qualified . . . by knowledge, skill, experience, training, or education[.]” Fed.

12 R. Evid. 702. The proponent of the expert bears the burden of proving admissibility. Lust By and

13 Through Lust v. Merrell Dow Pharmaceuticals, 89 F.3d 594, 598 (9th Cir. 1996).

14 The Supreme Court has set forth several factors that a district court should consider in

15 determining admissibility of expert testimony. Those factors are (1) testing, (2) peer review and

16 publication, (3) general acceptance in the scientific community, and (4) the known or potential rate

17 of error. Wagner v. County of Maricopa, 673 F.3d 977 (9th Cir. 2012) (citing Daubert, 509 U.S. 592-

18 93). The purpose of the factors is to determine whether the evidence is both reliable and relevant. The

19 test is flexible, and the inquiry “must be tied to the facts of a particular case.” Kumho Tire, 526 U.S.

20 at 150. “Whether Daubert's specific factors are, or are not, reasonable measures of reliability in a

21 particular case is a matter that the law grants the trial judge broad latitude to determine.” Id. at 153.

22 In light of the above identified requirements for expert testimony, the court turns to Mr. Larson’s

23 qualifications and expert opinions.

24 The first issue raised is whether Mr. Larson is qualified to provide expert testimony in the area

25 of high pressure liquid chromatography (“HPLC”) and mass spectrometry analysis. The second issue

26 is whether the methodologies applied by Mr. Larson satisfy the threshold requirements for

27 admissibility.

28 By way of background, chromatography “is the collective term for a set of laboratory

1 techniques for the separation of mixtures.” <http://wikipedia.org/wiki/chromatographic>; (Ct. Dkt. 38,
 2 Exh. F, Larson Report). HPLC “is a chromatographic technique used to separate a mixture or
 3 compounds in analytical chemistry and biochemistry with the purpose of identifying, quantifying and
 4 purifying the individual components of the mixture.” [http://wikipedia.org/wiki/high-](http://wikipedia.org/wiki/high-performance_liquid_chromatography)
 5 [performance_liquid_chromatography](http://wikipedia.org/wiki/high-performance_liquid_chromatography). The term “mass spectrometry” is a term referring to an
 6 “analytical technique that measures the mass-to-charge ratio of charged particles. It is used for
 7 determining masses of particles, for determining the elemental composition of a sample or molecule,
 8 and for elucidating the chemical structures of molecules.”
 9 http://wikipedika.org/wiki/Mass_spectrometry.

10 Mr. Larson’s Qualifications

11 The relevant record on Mr. Larson’s qualifications as an expert in the fields of HPLC and mass
 12 spectrometry is virtually non-existent. Mr. Larson, the Patent holder and CEO of Trivitis, graduated
 13 from UCLA in 1976 with a degree in mathematics. He does not have a degree in chemistry and
 14 testified that his only formal chemistry education was a high school chemistry class and college
 15 chemistry courses. (Ct. Dkt. 38, Exh. E at 70:19-20; Ct. Dkt. 31, Exh. E at 66:20-70:11). Mr.
 16 Larson’s post-college education is limited to week-long courses dealing with the FDA and seminars
 17 relating to “product labeling, and making claims.” (Ct. Dkt. 43 ¶5).

18 In opposition to the motion to exclude, Trivitis argues Mr. Larson, through experience and
 19 training, “has developed the requisite skill to testify as an expert on the chemistry issue present in this
 20 case. Mr. Larson’s Small Business Innovation Research Program grant applications document very
 21 specific research study and analysis of the chemistry issues involved in this case. Mr. Larson has been
 22 researching, studying, and experimenting in the field of art for more than eleven or twelve years.”
 23 (Oppo. at p.3: 13-18). Trivitis represents that Mr. Larson obtained experience through “studying and
 24 experimenting in the field of wine chemistry and amidating various favones for more than fifteen
 25 years.” (Oppo. at p.2:14-15). The difficulty with these arguments is that Trivitis provides no evidence
 26 to support the conclusory statement that Mr. Larson has “experience and training” in HPLC or mass
 27
 28

1 spectrometry.¹

2 Based upon the present evidentiary record, Trivitis fails to meet its threshold showing that Mr.
3 Larson is qualified as an expert to provide testimony on HPLC or mass spectrometry. Consequently,
4 the court does not consider this testimony upon ruling on the motions for summary judgment.

5 Mr. Larson's Methodology

6 Admissibility of expert scientific testimony must satisfy two threshold showings. First, the
7 court "must determine nothing less than whether the experts' testimony reflects 'scientific knowledge,'
8 whether their findings are 'derived by the scientific method,' and whether their work product amounts
9 to 'good science.'" Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1315 (9th Cir. 1995)
10 (quoting Daubert, 509 U.S. at 593) ("Daubert II"). Second, the court must determine the relevance of
11 the expert testimony. This second element is not at issue.

12 While the admissibility analysis on matters of scientific research presents the court with a
13 "daunting" task, Daubert II, 43 F.3d at 1316, the Ninth Circuit has set forth several guiding principles.
14 In the hierarchy of reliability, the Ninth Circuit noted that independent research performed independent
15 of the litigation is more reliable because it is conducted in the usual course of business and must
16 "normally satisfy a variety of standards to attract funding and institutional support." Id. at 1317. In
17 the case of litigation related research, like that at issue here, "the party proffering it must come forward
18 with other objective verifiable evidence that the testimony is based on 'scientifically valid principles.'" Id.
19 id. at 1318. One means of satisfying this showing is "by proof that the research and analysis
20 supporting the proffered conclusions have been subjected to normal scientific scrutiny through peer
21 review and publication." Id.

22 Ocean Spray challenges the methodology used by Mr. Larson in connection with his HPLC
23 analysis. Mr. Larson relied upon light scattering ("LS") detection instead of ultraviolet ("UV")
24 detection. Ocean Spray identifies its own expert as well as patent prosecutions that involved UV
25 detection in HPLC experiments involving catechins or catechin multimers. (Exhs. G, H, I, J). While
26 the experiments conducted by Mr. Larson used both light scattering techniques, he based his opinions
27

28 ¹ While Mr. Larson outsourced the actual testing of the products at issue, he designed the experiments, prepared the samples, and analyzed the resulting data.

1 only on the unconventional LS data.

2 Trivitis contends that Mr. Larson has many years of research experience “with the chemistry
3 involved in the field of art . . . [and has] conducted experiments of Ocean Spray’s product using
4 established, pre-litigation, methodologies and research.” (Oppo at p.5:12-16). The difficulty with this
5 conclusory statement is that Trivitis fails to cite any part of the record to substantiate this conclusion.
6 The court also notes that Trivitis repeatedly makes conclusory statements without citation to the record
7 (i.e. “Mr. Larson discovered that LS detection is an appropriate form of detection”; “testing was
8 conducted in a scientifically acceptable manner”; and “spectrometry analysis has been used for over
9 decades and is a good indicator regarding a sample’s purity,” Oppo. at p. 6:5-28). Without specific
10 citation to an evidentiary basis for these statements, Trivitis simply fails to carry its burden.

11 Trivitis also contends that HPLC and mass spectrometry are scientifically tested and accepted
12 methodologies. (Oppo. at p.4:26-28). This argument misses the mark. As noted by Ocean Spray, the
13 issue is whether Mr. Larson used accepted methods when he designed the HPLC and mass
14 spectrometry experiments, prepared the test samples, and analyzed the resulting data. On this issue,
15 Trivitis fails to meet its evidentiary burden.

16 Trivitis also argues that the affidavits attached to the declaration of Mr. Larson constitute
17 sufficient peer review to validate the employed methodologies. The court has located the majority of
18 the affidavits referenced in the Larson Declaration and concludes that Trivitis fails to establish
19 objective verifiable evidence that the testimony is based on scientifically valid principles.² Mr. Larson
20 declares that the declaration of Dr. Shillito confirms his approach and methodology. (Larson Decl.
21 ¶¶1-2). The declaration of Dr. Shillito, which the court discovered in the Larson Decl. Exh. D at p.3,
22 does not constitute a peer review publication. Dr. Shillito fails to set forth his qualifications with
23 respect to the issues at bar: HPLC and mass spectrometry. Id. In fact, Dr. Shillito declares “I don’t
24 claim to be an expert at every specific type of HPLC chromatography.” While Dr. Shillito does provide
25 an opinion on the chromatographs, the present issue concerns the methodologies used by Mr. Larson -
26 an opinion upon which Dr. Shillito does not opine. Mr. Larson also declares that Dennis Kristof

27
28 ² The court notes that it is not the role of the court to mine through the evidentiary submissions
of the parties to discover relevant documents. The court has only considered those factual assertions
that are supported by identifiable exhibits.

1 affirmed the results of his experiments. (Larson Decl. ¶5). The declaration of Mr. Kristof does not
 2 establish his qualifications as an expert on the methodologies used by Mr. Larson. (Larson Decl. Exh.
 3 A at p.4). Mr. Larson also declares that Dr. Cairns affirmed the results of his experiments. (Larson
 4 Decl. ¶5). The court could not readily locate Dr. Cairns' affidavit in the cited exhibit. The burden of
 5 Trivitis is not to show that the Larson Declaration is correct, only to show that it is reliable, something
 6 it fails to do.

7 In sum, the court concludes that Trivitis (1) fails to establish that Mr. Larson is a qualified
 8 expert and (2) fails to come forward with sufficient evidence to show that the methodologies and
 9 principles applied by Mr. Larson are based on scientifically valid principles. Consequently, the Larson
 10 Declaration and the Dale Shellhamer Declaration (who relies upon the Larson Declaration in reaching
 11 his opinions), are not admissible.

12 **Cross Motions for Summary Judgment**

13 Applying the properly constructed claims to Cranergy, Ocean Spray concludes that it did not
 14 infringe the Patent. First, Ocean Spray asserts that the alleged infringing substance in Cranergy,
 15 epigallocatechin gallate, does not meet the Patent's definition of "catechin" or "multimer." In essence,
 16 Professor Mitchell explains that the structural formula of epigallocatechin gallate is not a catechin
 17 multimer because it "does not contain any copy of catechin, as defined by the Court's construction,
 18 and certainly does not contain two copies of catechin." (Exh. E, Mitchell report at 11-12). He
 19 concludes from this analysis that "epigallocatechin gallate as that molecule exists in green tea is not
 20 a catechin molecule as catechin molecules are defined by the Court. . . [and] there is nothing to suggest
 21 [] that there exists two copies of catechin" such that it is a "catechin multimer" within the meaning of
 22 Plaintiff's Claims 10 and 11. Id. From this evidentiary showing, the court concludes, subject to an
 23 evidentiary challenge by Trivitis, that Cranergy does not infringe Plaintiff's Patent claims.

24 Based upon Ocean Spray's evidentiary showing, the burden shifts to Trivitis to show there is
 25 a genuine issue of material fact the allegedly infringing substance in green tea is, as claimed, a
 26 "catechin multimer" within the meaning of the Patent. The entirety of the opposition consists of the
 27 following statement:

28 This contention (referring to Professor Mitchell's opinions that the alleged
 infringing substance is not a "catechin multimer") becomes nonsense with a fair review

1 of “the facts”. It is a direct contradiction of well understood and well document (sic)
 2 in wine chemistry literature, but also in respected references like the SIGMA catalog,
 etc.

3 (Oppo at p. 5:4-9). The court concludes that this statement fails to raise a genuine issue of material
 4 fact. The statement does not cite to the evidentiary record or provide the court with any guidance to
 5 locate the evidentiary support for this conclusory statement. As noted earlier, it is not the role of the
 6 court to mine the evidentiary record to support a party’s arguments.³ Even assuming contradictory
 7 evidence may be found in the declaration of Mr. Larson, he is not a qualified expert witness, for the
 8 above stated reasons, and court has not considered his opinions. Accordingly, Plaintiff fails to raise
 9 a genuine issue of material fact that Cranergy violates the Patent.

10 Second, Ocean Spray asserts that Cranergy does not contain a bioactive agent “complexed”
 11 with a catechin multimer, a prerequisite for Plaintiff’s claims. The infringing contention alleges that
 12 Cranergy contains niacin as the “bioactive agent” which forms a complex with epigallocatechin
 13 gallate, the alleged catechin multimer. Professor Mitchell supervised a series of experiments to
 14 evaluate the ability of epigallocatechin gallate and similar compounds to form stable complexes with
 15 niacin in a solution of pH 3 (equivalent to the pH of Cranergy). Professor Mitchell concluded that the
 16 “chemistry of [these compounds] suggest that [they] would only have fleeting interactions in
 17 solutions” not detectable by her experiments and therefore not sufficient for delivery of niacin to the
 18 target sites. (Exh. E at 12-13, 25). From this evidentiary showing the court concludes, subject to an
 19 evidentiary challenge by Trivitis, that Cranergy does not violate the Patent.

20 Based upon this evidentiary showing, the burden shifts to Trivitis to show there is a genuine
 21 issue of material fact that the allegedly infringing product contains a “bioactive agent” “complexed”

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 23 ³ The court notes that Plaintiff’s motion for summary judgment similarly fails to identify
 24 contradictory evidence. For example, with respect to whether epigallocatechin gallate is a catechin
 multimer, Trivitis asserts:

25 Plaintiff submits that green tea extract indeed contains multimeric forms of the various
 26 catechin species. In that none of the evidence presented by Defendant’s expert rebuts
 this assertion, Plaintiff submits that it should be added to the list of undisputed material
 facts.


27 (Motion at p.10:4-8). Without citation to the evidentiary record, the court is unable to assess the
 28 evidentiary value of an unsupported factual assertion.

1 with” a “catechin multimer.” The entirety of the opposition consists of the statement: “Per, Digital
 2 Insight Corp., this is also a ‘**wholly unsupported conjecture.**’ Defendant offers no proof or evidence
 3 for such a conjecture.” (Oppo. at p. 5:13-14). The court concludes that this statement fails to raise
 4 a genuine issue of material fact. The statement does not cite to the evidentiary record or provide the
 5 court with any guidance to locate the evidentiary support for this conclusory contention. As noted
 6 earlier, it is not the role of the court to mine the evidentiary record to support a party’s arguments.
 7 Even assuming contradictory evidence may be found in the declaration of Mr. Larson, he is not a
 8 qualified expert witness, for the above stated reasons, and the court has not considered his opinions.⁴
 9 Accordingly, Plaintiff fails to raise a genuine issue of material fact that Cranergy violates the Patent.

10 In sum, the court grants summary judgment in favor of Defendant Ocean Spray and against
 11 Plaintiff Trivitis on the infringement claims alleged in Plaintiff’s complaint. The Clerk of Court is
 12 instructed to close the file.

13 **IT IS SO ORDERED.**

14 DATED: May 29, 2012


 Hon. Jeffrey T. Miller
 United States District Judge

16 cc: All parties
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26 ⁴ To the extent the statement in opposition may be construed as placing the evidentiary burden
 27 on Ocean Spray, Plaintiff misconstrues the nature of its burden on summary judgment. Plaintiff, as
 28 the party with the burden of proof at trial, must come forward with admissible evidenced to show there
 is a genuine issue for trial. Celotex, 477 U.S. 323. Plaintiff does not meet this burden.